

Message

From: KIRK, ANNETTE M [AG/1005] [annette.kirk@bayer.com]
Sent: 2/15/2019 11:02:12 PM
To: Adeeb, Shanta [Adeeb.Shanta@epa.gov]; Meadows, Sarah [Meadows.Sarah@epa.gov]; Kerr, Julia [kerr.julia@epa.gov]; Rowland, Grant [Rowland.Grant@epa.gov]
CC: Schmid, Emily [Schmid.Emily@epa.gov]; james.m.nyangulu@monsanto.com
Subject: FW: 524 Acetochlor product master labels under review
Attachments: 00524-00511_MON58494-DegreeXtra_Revised-Draft-MasterLabel_15Feb2019.pdf; 00524-00473_Harness-MasterLabel_Revised-Draft_15-Feb-2019.pdf; 00524-00480_HarnessXtra_Revised-Draft-MasterLabel_15-Feb-2019.pdf; 00524-00485_HarnessXtra5.6_revised-MasterLabel_15-Feb-2019.pdf

Importance: High

Hello Shanta, Sarah, Julia and Rowland,

Per Emily's message below I'm attaching revised versions of the master label for each of the registrations listed here:

- MON 58494 Herbicide (alternate brand: Degree Xtra), reg. no. 524-511 (Shanta Adeeb)
- Harness Herbicide, EPA Reg. No. 524-537 (Sarah Meadows)
- Harness Xtra Herbicide, EPA Reg. No. 524-480 (Julia Kerr)
- Harness Xtra 5.6L Herbicide, EPA Reg. No. 524-485 (Grant Rowland)

The details of my request are below in my message from December 10th, but briefly, I'd like the revised versions attached here to be substituted for those previously submitted, for final stamping. The master label for reg. no. 524-511 is directly linked to the tolerance amendment petition for the safener, furilazole (PP IN-11139; Decision # 538804) to add tolerances for sweet corn commodities. The master labels for the other registrations are indirectly related in that we were required to submit them with references to sweet corn removed, and the attached versions have sweet corn added back in.

I'm providing pdf copies since Reuben previously indicated that a pdf is needed to run a comparison with the current version. If you'd like, I have Word versions available with changes marked that I could also send.

I'd be happy to discuss details of the revisions at any time, just let me know.

Best regards,
Annette

Annette Kirk
Global Regulatory Affairs Manager

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Bayer U.S. – Crop Science
Regulatory Science North America
Monsanto Company
700 Chesterfield Parkway West
St. Louis, MO 63017, U.S.A.
Tel: +1 636-737-9575
Cell: +1 314-560-6576
E-mail: annette.kirk@bayer.com
Web: <http://www.bayer.com>

From: Schmid, Emily <Schmid.Emily@epa.gov>
Sent: Wednesday, February 13, 2019 6:48 AM
To: KIRK, ANNETTE M [AG/1005] <annette.kirk@bayer.com>
Cc: NYANGULU, JAMES M [AG/1920] <james.m.nyangulu@monsanto.com>
Subject: RE: 524 Acetochlor product master labels under review

Hi Annette,

Sorry that it has taken me so long to respond to this!

The attachments didn't come through but I looked up the reviewers and they should be able to help you.

- MON 58494 Herbicide (alternate brand: Degree Xtra), reg. no. 524-511 Shanta Adeeb
- Harness Herbicide, EPA Reg. No. 524-537 Sarah Meadows
- Harness Xtra Herbicide, EPA Reg. No. 524-480 Julia Kerr
- Harness Xtra 5.6L Herbicide, EPA Reg. No. 524-485 Grant Rowland

Best regards,
Emily

From: KIRK, ANNETTE M [AG/1005] <annette.kirk@bayer.com>
Sent: Wednesday, February 06, 2019 6:44 PM
To: Schmid, Emily <Schmid.Emily@epa.gov>
Cc: james.m.nyangulu@monsanto.com
Subject: RE: 524 Acetochlor product master labels under review

Hi Emily,

I got an "undeliverable" message back and doubled checked to find that I've been using the wrong email address for you! Hopefully this makes it through to you.

Best regards,
Annette

From: KIRK, ANNETTE M [AG/1005]
Sent: Wednesday, February 06, 2019 5:29 PM
To: emily.schmid@epa.gov
Cc: NYANGULU, JAMES M [AG/1920] <james.m.nyangulu@monsanto.com>
Subject: RE: 524 Acetochlor product master labels under review
Importance: High

Hello Emily,

I hope you're doing well and that you and your team have been able to make a dent in some of the backlog since the shutdown.

Sorry to bug you, but I wanted reach out and see if could send you or the assigned reviewer (as email attachments) this week, the revised versions of the master labels for these registrations, to substitute for the versions you have pending (details in my message below), for final stamping.

- MON 58494 Herbicide (alternate brand: Degree Xtra), reg. no. 524-511 Shanta Adeeb
- Harness Herbicide, EPA Reg. No. 524-537 Sarah Meadows
- Harness Xtra Herbicide, EPA Reg. No. 524-480 Julia Kerr
- Harness Xtra 5.6L Herbicide, EPA Reg. No. 524-485 Grant Rowland

I'm expecting to receive a request to extend the PRIA due date for the tolerance amendment petition for the safener, furilazole (PP IN-11139; Decision # 538804), but haven't seen that yet, so this seems to me to be the perfect time to get these labels switched out.

I'd greatly appreciate hearing from you.

Many thanks
Annette

Annette Kirk
Global Regulatory Affairs Manager

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Bayer U.S. – Crop Science
Regulatory Science North America
Monsanto Company
700 Chesterfield Parkway West
St. Louis, MO 63017, U.S.A.
Tel: +1 636-737-9575
Cell: +1 314-560-6576
E-mail: annette.kirk@bayer.com
Web: <http://www.bayer.com>

From: KIRK, ANNETTE M [AG/1005]
Sent: Monday, December 17, 2018 2:39 PM
To: emily.schmid@epa.gov
Subject: RE: 524 Acetochlor product master labels under review

Hello Emily,

I just wanted to check-in to see if you had the chance to look at my message below, and heard my voice message from Thursday of last week. If you happen to be in the office at all this week and you have a few minutes to give me a call, I'll be here through Wednesday, Dec. 19th. After that I'm out for the Holidays and back in the office on January 3rd.

Many thanks,
Annette

Annette Kirk
Global Regulatory Affairs Manager

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Regulatory Science North America
Monsanto Company
700 Chesterfield Parkway West
St. Louis, MO 63017, U.S.A.
Tel: +1 636-737-9575
Cell: +1 314-560-6576
E-mail: annette.kirk@bayer.com
Web: <http://www.bayer.com>

From: KIRK, ANNETTE M [AG/1005]
Sent: Monday, December 10, 2018 5:56 PM
To: emily.schmid@epa.gov
Subject: 524 Acetochlor product master labels under review

Dear Emily,

I understand that you are "acting" PM for Team 25? I'm writing to inquire about some "master labels" I have pending review for several acetochlor product registrations that I'm responsible for, and to ask if I could substitute updated versions now, for review prior to final stamping.

I've made a number of updates to these labels, which for the most part have not been significantly update since the mid-1990s; no significant changes to use instructions, but rather, mostly re-formatting to break out and move existing

language under new section headings for better readability and to be in line with modern ag practices; some minor grammatical wording changes; and updates to tank mixture products, etc.

One of these master labels is for MON 58494 Herbicide (alternate brand: Degree Xtra), reg. no. 524-511, which I submitted on Feb. 12, 2018 with the tolerance amendment petition for the safener, furlazole (PP IN-11139; Decision # 538804) to add tolerances for sweet corn commodities. The proposed rule published in the FR on October 18, 2018. I believe the PRIA due date for the tolerance amendment is early January, but I'm unsure.

The other three master labels, listed below, were submitted in April, 2018 to comply with an Agency Initiated Action in a letter dated March 28, 2018, requiring us to remove references to use in/on sweet corn. This Action was required due to the tolerance petition related to furlazole, mentioned above. These three other master labels have also been updated (similar revisions to those described above for reg. no. 524-511) and I would like to substitute the versions submitted in April, for new versions.

- Harness Herbicide, EPA Reg. No. 524-537
- Harness Xtra Herbicide, EPA Reg. No. 524-480
- Harness Xtra 5.6L Herbicide, EPA Reg. No. 524-485

There are number of changes (although as I said, mostly formatting) that I'm sure the reviewer will want to look at, but I'd be happy to provide more details when I send the updated versions. I realize the PRIA due date is fast approaching, but I've not seen the Final Rule publish yet, so if it would help, and there is an opportunity, I'd be open to agreeing to extending the due date. It is only the label for reg. no. 524-511 that is actually linked to the PRIA action, so if you were open to starting with that one, perhaps the other could be looked at a little later?

Let me know your thoughts. If there is an assigned review that I should contact, please let me know.

I could give you a call to discuss this or please feel free to call me.

Many thanks
Annette

Annette Kirk
Global Regulatory Affairs Manager

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Regulatory Science North America
Monsanto Company
700 Chesterfield Parkway West
St. Louis, MO 63017, U.S.A.
Tel: +1 636-737-9575
Cell: +1 314-560-6576
E-mail: annette.kirk@bayer.com
Web: <http://www.bayer.com>

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